

**REMARKS**

Applicants acknowledge with thanks the interview of May 27, 2004, granted by Examiner Mertz, during which the outstanding issue regarding patentable utility was addressed with the undersigned representative of Applicants. Applicants further acknowledge the withdrawal of rejections as noted in the Office Action at paragraph 3. The sole outstanding issue is a rejection of claims under 35 U.S.C. §§ 101/112, first paragraph (enablement). Office Action at paragraph 4. The following remarks are believed to overcome the rejection and to place the application in condition for allowance.

The Patent Office rejected claims 1, 4-8, 10, 51-55, 70, and 72 under 35 U.S.C. § 101 for assertedly lacking specific and substantial utility. (Office Action at paragraph 6.) In support, the Examiner asserted that "[t]he claimed invention is directed to a polynucleotide encoding a polypeptide of as yet undetermined function or biological significance. Thus, since there is no biological activity disclosed for the protein encoded by the claimed nucleic acid, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility." Office Action at page 4. Applicants respectfully disagree.

A biological activity of the polynucleotides of the invention is detectably greater expression in testis tissue than in other tissues. That activity is disclosed in the application as filed, and that activity provides a specific and substantial utility for the claimed subject matter. More particularly, the application discloses that the gene corresponding to SEQ ID NO: 1 has been shown to be expressed predominantly in testis tissue. Detecting that expression can be by way of using polynucleotides of the invention as probes to detect mRNA in a biological sample. Additionally, polynucleotides, vectors, and host cells of the invention can be used to express the protein encoded by SEQ ID NO: 1. Further, antibodies can be raised against the recombinant protein, and the antibodies can be used in standard immunoassays to detect the encoded protein expressed in cell membranes on the surface of cells. One of skill in the art would appreciate that these disclosures establish a use for the claimed subject matter in the form of a specific, substantial and credible diagnosing of testicular cancer cell metastasis.

Metastasis of cancer cells, such as cancerous testis cells, was well known in the art. As one of skill in the art would recognize, the loss of contact inhibition and migration

characteristic of metastasizing cancer cells would result in such cells being found in atypical *in vivo* locations for cells of a given tissue type, such as testis tissue. Detection of metastasized cancer cells by specifically detecting cells of a given tissue type in atypical or abnormal *in vivo* locations was a utility well established in the art. The subject matter of the invention was disclosed as useful in detecting cells of the testis, and this function would have been recognized by one of skill in the art as providing a method for diagnosing metastasized testicular cancer cells, a patentable utility.

None of the bases for rejecting the pending claims under § 101 undermines or challenges this assertion of a patentable utility in diagnosing testicular cancer cell metastasis. In the Office Action, the Patent Office asserted that all non-ubiquitously expressed proteins are expressed in a tissue-specific manner and could be used as tissue markers, analogizing the situation to a throw-away utility such as the use of polynucleotides as molecular weight markers. That position, however, is based on an improper generalization of the claimed subject matter. The polynucleotides of the present claims are not disclosed as useful tissue markers for at least one specific tissue chosen from among all known tissues. The claimed subject matter is disclosed as being useful in identifying a particular tissue, testis tissue. Not all non-ubiquitously expressed proteins are useful in detecting testis tissue, and the Patent Office has not supported even a single example of a known protein specifically expressed in testis tissue. Accordingly, the assertion that the claimed subject matter is useful as a testis tissue marker is not analogous to the assertion of a throw-away utility such as use of a polynucleotide as a molecular weight marker.

Even if an example of a polynucleotide known to be expressed in a testis-specific manner were provided on the record, moreover, such an example would not provide a proper basis for concluding that an alternative means for specifically detecting testis tissue could not be patentably useful. A patentable utility does not have to be a unique, or new, utility. The existence of alternatives is uninformative on the issue of whether an asserted use is a patentable use, unless all members of a class would be alternatives. As established above, there is no class of biological material (e.g., polynucleotide, antibody) in which each member would provide an alternative approach to specifically identifying testis tissue as a result of predominant expression therein.

The Patent Office also asserted that a patentable utility, such as the detection of cancer cells, had not been supported in the application as filed because there was no disclosure of detectably different expression levels in healthy and cancerous testis cells. As noted above, however, the application as filed does support the use of the claimed subject matter to detect metastasized testicular cancer cells, with the discrimination between healthy and metastasized cancer cells being provided by the *in vivo* location of such cells, as would have been known in the art. Accordingly, the claimed subject matter is supported by a patentable utility in the form of specifically detecting metastasized testicular cancer cells. Moreover, the detection of metastasized testicular cancer cells is a substantial, or real world, use of the claimed subject matter. Thus, the claimed subject matter is supported by a specific and substantial utility, and is not simply a subject for further research.

For the foregoing reasons, Applicants submit that the claimed subject matter has been disclosed as useful in detecting, or diagnosing, metastasized testicular cancer cells, a use that is (1) specific in diagnosing a stage of specific types of cancer, (2) substantial in being presently realized for the detection of a serious medical condition, and (3) credible as shown by the reasoning provided above (and Applicants acknowledge that the Patent Office has not challenged credibility). Consequently, the subject matter of the pending claims is supported by a patentable utility. Accordingly, the rejection of claims 1, 4-8, 10, 51-55, 70 and 72 under 35 U.S.C. § 101 has been overcome and should be withdrawn.

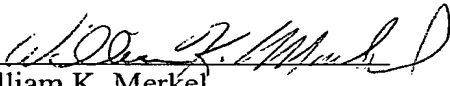
Claims 1, 4-8, 10, 51-55, 70 and 72 were also rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement, based on the effective assertion that one cannot teach how to use that which has no use. The preceding remarks have established that the claimed subject matter is supported by the disclosure of a patentable use in detecting metastasized testicular cancer cells. Accordingly, the sole basis for rejecting the claims under § 112, first paragraph, for lack of enablement, has been overcome and, for that reason, the rejection of claims 1, 4-8, 10, 51-55, 70 and 72 under 35 U.S.C. § 112, first paragraph, for lack of enablement, should be withdrawn.

**CONCLUSION**

For all of the foregoing reasons, the outstanding rejection of the claims under 35 U.S.C. §§ 101/112, first paragraph, for lack of enablement, has been overcome and each of the pending claims is in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: June 2, 2004

Respectfully submitted,

By   
William K. Merkel  
Registration No.: 40,725

MARSHALL, GERSTEIN & BORUN LLP  
233 S. Wacker Drive, Suite 6300  
Sears Tower  
Chicago, Illinois 60606-6357  
(312) 474-6300  
Attorneys for Applicants